## PROTOCOL OUTLINE

PROTOCOL NUMBER: WHOTI G-040

## PROTOCOL TITLE:

Effect of Frequent Daily Use for Four Weeks of a MICRODENT® - containing, Sorbitol-based, Chewing Gum in Reducing Dental Plaque Accumulation When Compared to a Placebo Gum and A No-Chewing Control Period:

A Double Blind, Crossover Treatment Design

PRINCIPLE INVESTIGATOR: Thomas Schiff, D.M.D.

CLINICAL TRIAL SITE: Univ. of the Pacific School of Dentistry

TECHNICAL SPONSOR: Ira Hill, Ph.D., WhiteHill Oral Technologies, Inc.

LICENSEE SPONSOR: Richard Peck, President, Ranir-DCP, West Orange, NJ GUM MANUFACTURER: Gary Kehoe, President, Gum Tech, Inc., Phoenix, AZ

Subjects: 20 to finish

Product Use Instructions:

Chew two pieces of the assigned chewing gum for 20 minutes after each meal [3X Daily].

Oral Hygiene Instructions:

Subjects are to follow their normal and customary tooth brushing habits, using the same toothbrush and toothpaste as they normally do.

Subjects are not to use any mouthwash, mints or chewing gums except those provided for the study.

Last tooth brushing before reporting to the clinic for each plaque examination is to be the evening before (12 hour plaque regrowth).

DAY 1 Subjects scored for Plaque (Baseline)

Expanded Turesky Modification of Quigley-Hein (Shaver-Schiff)

Soft Tissue Assessment Recorded

Rubber Cup prophy to reduce plague scores to zero.

Assign one-half the subjects Gum # 050, the other half Gum # 315 Instruct Subjects on Product Use and Oral Hygiene Instructions

Provide Assigned Product for One Month's Use.

DAY 28 Subjects scored for Plaque (Final)

Record Soft Tissue Assessment, noting any treatment related changes

Rubber Cup prophy to zero

Supply sugar-free breath mints for the "No-Chewing Gum Control" period.

## **Chewing Gum Protocol Outline**

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DAY 56 Subjects scored for Plaque ("No-Gum Chewing Control") Final.

Assign Cross-Over Gum Product and repeat instructions

DAY 84 Subjects scored for Plaque (Final)
Record Soft Tissue Assessment, noting any treatment related changes

Submit Raw Data to Technical Sponsor for Statistical Analysis and Issuance of Final Report [containing Full Protocol, CV of Principle Investigator, Informed Consent Documents, IRB Approval, Soft Tissue Assessment.] Statistical Analysis to include twin-tailed "t" test and other parametric and non-parametric analyses as may be deemed suitable.

Thomas Schiff, DMD

Principle Investigator

date

Ira Hill, Ph.D.
Technical Sponsor